



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,828	08/31/1998	ANDERS BERKENSTAM	10806-65	4054

7590 01/15/2002

HOLLY D KOZLOWSKI
DINSMORE & SHOHL
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 01/15/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental
Office Action Summary

Application No. 09/143,828	Applicant(s) Berkenstam et al.
Examiner Michael Pak	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Oct 3, 2001
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 13-17, 29-31, 33, and 42-55 is/are pending in the application.
- 4a) Of the above, claim(s) 29-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 13-17, 33, and 42-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) Interview Summary (PTO-413) Paper No(s). 17
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

SUPPLEMENTAL DETAILED ACTION

Response to Amendment

1. Applicant indicated in an interview summary (Paper NO. 16 attached) that a wrong action was mailed from the USPTO on 12-20-01 (Paper No. 15). Applicant is advised that the previous office action mailed 12-20-01 (Paper No. 15) has been vacated and removed from the application because application pending before the USPTO should be confidential. Examiner requests that the applicant return the wrong action mailed in Paper No. 15. The response set forth below was the action which should have been mailed.
2. Applicant's response to office action filed 3 October 2001 (Paper No. 14) has been received.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments filed 3 October 2001 (Paper No. 14), have been fully considered but they are not found persuasive.
5. Applicant's request for reconsideration of restriction is not found persuasive.

The restriction requirement remains final.

6. This application contains claims 29-31 drawn to an invention non-elected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) MPEP § 821.01.

Claim Rejections - 35 USC § 101

7. Claims 1-9, 13-17, 32-33 and 42-55 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that the utility of the claimed invention is similar to the utility of vitamin D. However, the claimed invention is drawn to an orphan receptor which has no known ligand. Further experimentation is required to determine the ligand for the orphan receptor and the orphan receptor has no known utility. The homology to vitamin D receptor is not sufficient to establish that the claimed orphan receptor is a vitamin D receptor since many nuclear receptors have close homology yet have separate ligands with unique function which the orphan receptor does not have at the time of the invention. The claimed invention lacks a specific and substantial utility.

Claims 1-9, 13-17, 32-33 and 42-55 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

8. Claims 1-9, 13-17, 32-33, 42-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9, 13-17, 32-33, and 42-55 encompass the term "substantially the same" or "recombinant type" whose metes and bounds ambiguous because no specific structural limitations are provided. Claims encompass sequence similarity with hVDR or xONR1 domains whose metes and bounds are not clear. Applicants argue that the specification on page 7 defines the term "substantially the same", but the definition encompasses derived sequences which appears more generic than the term alleles and the metes and bounds are not clear.

9. Claims 1-9, 13-17, 32-33, and 42-55 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass the DNA or vectors and cells comprising the DNA encoding a variant protein which is naturally occurring but not disclosed in the specification nor to one of skilled in the art. Claimed DNA encoding protein variants encompass a large genus of nuclear receptors which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring receptor is not known. The essential feature of the claimed invention is DNA encoding an orphan receptor whose function is not known. *University of California v. Eli Lilly and Co.* (CAFC) 43 USPQ2d 1398 held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of orphan receptors structure cannot be envisioned.

Claim Rejections - 35 USC § 102

10. Claims 1-9, 13-15, 32-33, and 42-53 are rejected under 35

U.S.C. 102(e) as being anticipated by Kausch et al. (A).

The reason for the rejection has been set forth previously.

Applicants argue that Kausch teach chromosomal DNA.

However, the chromosomal DNA comprises the claimed nucleic acid especially the generic claims. The newly amended claims are still generic and encompasses the DNA of Kausch.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak
Michael Pak
Primary Patent Examiner
Art Unit 1646
18 February 2001